

REMARKS

The specification has been amended in accordance with the Examiner's suggestions in order to correct a number of informalities.

With regard to the drawings, in view of the present amendment to the specification eliminating the reference numbers "19" and "72". There is no need to submit new drawings with these added reference numbers.

The Examiner has objected to claim 6 because of the use of the limitation "Botox". In response, the Applicants have replaced "Botox" with "botulinum toxin".

Independent claim 1 has been amended and new independent claim 9 has been added to more clearly define the present invention and more specifically the present invention has been defined as utilizing a manually operated control, or control rod, disposed in an operative parallel relationship with a plunger rack and slidable therealong for movement of the plunger rack.

As more specifically set forth in claim 9, an injecting pall is pivotally mounted to one end of the control rod for engaging the plunger rack for moving the plunger rack in a forward direction and in addition a withdrawing pawl is disposed for engaging the control rod for moving the plunger rack in a reverse direction. No separate levers or actuators are necessary for changing pawl engagement as is necessary in prior art devices and further a finger accessible button which is attached to the

control rod and extending exterior to a shell is provided for causing sliding movement of the control rod.

Original claims 1-4, 7-8 were rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 5,891,106 to Butuzov. Traverse of this rejection will be based upon the amended claims.

The Applicants that anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of the claimed invention. RCA Corp. v. Applied Digital Data Systems, Inc., 221 USPQ 385 (Fed. Cir. 1984); In re Sun, 31 USPQ 2d 1451 (CAFC 1993); Advanced Display Systems, Inc. v. Kent State University, 540 USPQ 2d 1673 (CAFC 2000).

Further, the Examiner must identify wherein each and every facet of the claimed invention is disclosed in the applied reference. Ex Parte Levy, 17 USPQ 2d 1461 (USPTO Board of Patent Appeals and Interferences 1990).

In addition, the Applicants submit that anticipation must meet strict standards and unless all of the same elements are found in exactly the same situation and united in the same way to form identical function in a single prior art reference, there is no anticipation. Tights, Inc. v. Acme-McCary Corporation, et al., 191 USPQ 305 (CAFC 1976).

With this criteria in mind, it is clear that there is no anticipation of the amended claims. Specifically, there is no disclosure of a manually operated control rod which

is disposed in an operative parallel relationship with the plunger rack for moving the rack in a forward and a reverse direction.

Clearly, Butuzov, et al. includes no parallel disposed control rod for engagement with a plunger rack. This being the case, the Applicants submit that the Examiner has not made a prima facie case of anticipation under 35 USC 102(b) for claims 1-4 and 7-8 and newly added claim 9. Accordingly, the Examiner is respectfully requested to withdraw this rejection of the claims based upon 35 USC 102(b).

Claims 1-4, and 7-8 have also been rejected by the Examiner under 35 USC 102(b) as being anticipated by U.S. 2,892,457 to Sturtz. Again, on the basis of the criteria hereinabove set forth for finding anticipation under 35 USC 102(b), Sturtz is lacking in any teaching or suggestion of the use of a control rod which is disposed in a parallel relationship for engagement for injecting and withdrawing pawls for moving the plunger rack.

Further there is no teaching or suggestion of an injecting pawl which is pivotally mounted to one end of the parallel mounted control rod. The closest structure of Sturtz is a longitudinally extended lever 71 which is pivotally carried at an upper portion of the trigger assembly 64 by means of a transverse pin 72. However, this is nowhere similar to the control rod of the present invention which is disposed for slidable movement along the plunger rack.

Accordingly, the Applicants submit that the Examiner has not made a prima facie case of anticipation for claims 1-4,7-8 and newly added claim 9 under 35 USC 102(b) on the basis of the Sturtz reference and therefore respectfully requests the Examiner to withdraw this rejection.

Claim 5 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Butuzov, et al. In this rejection, the Examiner states that Butuzov discloses the invention substantially as claimed except for expressly disclosing that the control is configured to inject medication in the range between 5 μ l and 1 ml. The Examiner acknowledges that Butuzov is silent as to the exact medication dosage injection or withdrawn for each pawl.

However, the Examiner concludes it would have been obvious to one of having ordinary skill in the art at the time the invention was made to modify the control as taught by Butuzov, et al. with a capability of range of between 5 μ l and 1 ml since it was known in the art that injection amounts of analgesia is used to provide injection amounts on a drop to drop basis.

In view of the arguments hereinabove set forth with regard to deficiencies of Butuzov in showing a control rod, the applicants submit that a prima facie case of obviousness under 35 USC 103(a) has not been established on the basis of the Butuzov, et al. reference.

First, there is no teaching in Butuzov, as acknowledge by the Examiner, with regard to the dosing amounts and secondly, there is no suggestion of the control rod

structure defined by the amended claims now pending in the present application. Therefore, the Applicants respectfully request the Examiner to withdraw the rejection of claim 5 under 35 USC 103(a) on the basis of the Butuzov reference.

Claim 5 has also been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Sturtz. This rejection is based upon the same line of reasoning professed by the Examiner with the rejection of claim 5 on the basis of Butuzov.

In response, the Applicants respectfully reiterate the arguments hereinabove set forth with regard to the rejection of claim 5 under 35 USC 103(a) on the basis of Butuzov and respectfully request the Examiner to withdraw the rejection of claim 5 under 35 USC 103(a) on the basis of Sturtz.

Claim 6 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Butuzov in view of U.S. 5,674,205 to Pasricha, et al. In this rejection, the Examiner states that Butuzov discloses the invention as substantially as claimed except for expressly disclosing the medicament as Botox. The Examiner therefore looks to Pasricha, et al. for teaching that is known to use in medicament to be Botox for the purpose of injection a neurotoxin.

The Applicants respectfully reiterate the arguments hereinabove set forth. It must be recognize that Butuzov, et al. teaches nothing with regard to a control rod

disposed in a parallel relationship with a plunger rack and combination pawls for movement of the rack in stepwise forward and reverse directions. In view of a lack of any further teaching in this regard by Pasricha, et al., the Applicants claim that a prima facie case of obviousness has not been made on the basis of 35 USC 103(a) on the combination of Butuzov and Pasricha, et al. Withdrawal of this rejection is respectfully requested by the Applicants.

Claim 6 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Sturtz in view of Pasricha, et al. The Examiner utilizes the identical reasoning as set forth with regard to the rejection of claim 6 on the basis of 35 USC 103(a) utilizing Butuzov and Pasricha, et al.

Therefore, the Applicants respectfully reiterate the arguments hereinabove set forth and traverse of this rejection and maintain that the Examiner has not made a prima facie case of obviousness under 35 USC 103(a) of claim 6 on the basis of the Butuzov and Pasricha, et al. references.

In view of the arguments hereinabove set forth and amendment to the claims and specification, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of

record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectfully requested.

Respectfully submitted,



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